

49 FR 1139

From LexisNexis:

4

FEDERAL REGISTER

49 FR 1139

January 9, 1984

National Toxicology Program; Chemicals (13) Nominated for Toxicological Testing; Request for Comments

SUMMARY: On November 8, 1983, the Chemical Evaluation Committee of the **National Toxicology Program** (NTP) met to review 12 chemicals and one group of substances nominated for toxicology testing and to recommend the types of testing to be performed. With this notice, the NTP solicits public comment on the 13 chemicals listed herein.

For Further Information and Submission on Comments, Contact: Dr. Dorothy Canter, Assistant to the Director, **National Toxicology Program**, Room 2B55, Building 31, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-3511.

TEXT: SUPPLEMENTARY INFORMATION: As part of the chemical selection process of the National Toxicology Program, nominated chemicals which have been reviewed by the NTP Chemical Evaluation Committee (CEC) are published with request for comment in the Federal Register and *NTP Technical Bulletin*. This encourages outside individuals and groups to participate in the NTP chemical evaluation process thereby helping the NTP to make better informed decisions as to whether to select, reject or defer chemicals for testing.

Relevant comments and data submitted in response to this request are reviewed and summarized by NTP technical staff and then forwarded to the NTP Board of Scientific Counselors for its evaluation of the nominated chemicals and to the NTP Executive Committee for its decision-making about testing. The NTP chemical selection process is summarized in the Federal Register, April 14, 1981 (46 FR 21818), and also in the NTP FY 1983 Annual Plan, pages 213-215.

On November 8, 1983, the CEC evaluated 12 chemicals and one group of substances nominated to the NTP for toxicological testing. The table below lists the chemicals and the group of substances, the Chemical Abstracts Service (CAS) registry numbers, where applicable, and the types of testing recommended by the CEC.

Chemical	CAS No.	Committee recommendation
1. Arsine	7784-42-1	Comparative study of chemical disposition of arsine and arsenic trioxide.
2. Black newsprint inks		Skin painting carcinogenicity of two types of ink and of their petroleum pitch and petroleum oil vehicle components. Chemical analyses of inks and their components to be performed prior to initiation of carcinogenicity studies.
3. Cinquasia red	1047-16-1	Inhalational chemical disposition study.
4. C.I. Acid Yellow 151	12715-61-6	No testing.
5. C.I. Basic Red 18	14097-03-1	Dermal chemical disposition study.
6. C.I. Direct Red 80	2610-10-8	No testing.
7. C.I. Direct Yellow 4	3051-11-4	Chemical disposition study.

Chemical	CAS No.	Committee recommendation
		Carcinogenicity study it absorption demonstrated.
8. C.I. Disperse Brown 1	23355-64-8	No testing.
9. D&C Yellow No. 11	8003-22-3	Salmonella assay. Dermal chemical disposition study. Oral carcinogenicity study.
10. Luminol	521-31-3	Salmonella assay. Dermal chemical disposition study.
11. Malathion	121-75-5	Defer pending receipt of reproductive studies from EPA.
12. Picloram	1918-02-1	Defer pending receipt of data from EPA.
13. Stannous flouride	7783-47-3	No testing.

The chemicals malathion and picloram were previously tested by the NTP in various toxicology test systems. Malathion was negative for carcinogenicity in feeding studies in male and female rats and mice. The chemical was also negative in the *Salmonella* microsomal assay when tested in four strains of the bacteria both with and without metabolic activation. Malathion was positive for both chromosomal aberrations and sister chromatid exchanges when tested in cultured Chinese hamster ovary cells.

In an NCI/NTP feeding study of picloram in male and female rats and mice, an increased incidence of neoplastic nodules of the liver in female rats was associated with treatment with picloram. No tumors were observed in male or female mice or male rats at incidences that could be significantly associated with treatment. On the basis of these results, it was judged that there is equivocal evidence of carcinogenicity for picloram. The chemical was negative in the *Salmonella* assay in all four strains tested both with and without metabolic activation. Picloram did not induce sexlinked recessive lethal mutations when tested in *Drosophila*. It currently is being tested in cultured Chinese hamster ovary cells for its ability to induce chromosomal aberrations and sister sister chromatid exchanges.

Although stannous fluoride has not previously been selected for testing by the NTP, two related compounds, namely stannous chloride and sodium fluoride, have been. There was no evidence of carcinogenesis when stannous chloride was tested in a feed study in male and female rats and mice. The chemical was also negative in the *Salmonella* assay in all four strains tested with and without activation. Sodium fluoride is currently being administered in the water to rats and mice in a carcinogenesis study. It was negative in all four strains tested in the *Salmonella* assay but yielded positive results in the L5178Y mouse lymphoma assay.

None of the other chemicals evaluated for testing at the November 8, 1983 meeting have previously been selected by the NTP for any type of toxicological testing.

Interested parties are requested to submit pertinent information. The following types of data are of particular relevance:

(1) Completed, ongoing and/or planned toxicological testing in the private sector including detailed experimental protocols and, in the case of completed studies, resultant data.

(2) Modes of production, present production levels, and occupational exposure potential.

(3) Uses and resulting exposure levels, where known.

(4) Results of toxicological studies of structurally related compounds.

Please submit all information in writing by (thirty days after date of publication). Any submissions received after the above date will be accepted and utilized where possible.

Dated: January 3, 1984.

David P. Rall,

M.D., Ph. D., Director, National Toxicology Program.

[FR Doc. 84-405 Filed 1-6-84; 8:45 am]

49 FR 1139

BILLING CODE 4140-01-M